DISC Monitoring Report

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| **Protocol Information** |
| **Title** | <Insert protocol title> |
| **Protocol No.** | <Insert protocol number(s)> |
| **Protocol Version** | <Insert version number and date of current protocol> |
| **PI** | <Insert PI’s first and last name with their academic degree> |
| **Sponsor(s)** | <Insert all sponsors, if applicable> |
| **Institution(s)** | <Insert all institutions including the University of Florida> |
| **Phase** | <Insert study’s phase> |
| **Age (Adults/Children)** | <Insert either Adult, Children, or Both> |
| **IND Number(s)** | <Insert IND number(s), if applicable> |

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| **Report Details** |
| **Date Report Issued** | <Insert date that the report is being issued> |
| **Date of Last Data Review** | <Insert date of last DISC meeting> |
| **Data Cutoff Date** | <Insert the date of the data snapshot for the analyses in this report> |
| **DISC Review Frequency** | <Insert frequency of DISC reviews> |
| **DISC Meeting Date** | <Insert date of the scheduled meeting> |
| **Prepared by** | <Insert DISC Administrator information> |

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| **Protocol Synopsis** |

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| **Protocol Accrual** |
| **Protocol Target Accrual** |  | **CC Total Accrual Goal** |  | **CC Annual Accrual Goal** |  | **Accrual Duration (Months)** |  |
| **Date Opened** |  | **Accrual To Date** |  | **Expected Accrual Completion Date** |  |  |  |

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| **Study Site Status** |
| <Insert study site status>{Example text}Two of the 3 study sites have been activated. The third will be activated this month. |

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| **Objectives** |
| <Insert study objectives> |

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| **Design** |
| <Briefly describe study design> |

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| **Schema** |
| <Insert the schema> |

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| **Treatment** |
| **Step** | **ARM** | **Modalities** | **Drug** | **Levels** |
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| **Inclusion Criteria** |
| <List inclusion criteria> |

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| **Exclusion Criteria** |
| <List exclusion criteria> |

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| **Study Outcomes** |
| <Briefly describe study outcomes> |

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| **Study Stopping Rules** |
| <Clarify stopping rules or suspension guidelines> |

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| **Have any study stopping rules been met?** |
| <List any situations where stopping rules have been met>{Example text}“No stopping rules have been met since the previous DISC review.”Or “There are no new “Alerts” since the previous DISC review.” |

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| **Quality Management** |
| <List the frequency of DISC reviews and their dates>{Example text}Quality management reviews are performed quarterly and were last completed on February 3, 2015 and February 3, 2016. |

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| **Protocol Reviews** |

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| **DISC Action History** |
| **Review Date** | **Review Reason** | **Review Type** | **Decision** | **Summary** |
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| **Protocol Accrual** |

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| **Sequence No.** | **Arm** | **Level** | **Study Site** | **Consent Signed Date** | **On Study Date** | **Off Treatment Date** | **Off Study Date** | **Expired Date** |
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| **Protocol Accrual History** |

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| **Accrual by Year** |
| **Year** | **Accrual this Year** | **Cumulative Accrual** |
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| **Accrual by Quarter** |
| **Quarter** | **Accrual this Month** | **Cumulative Accrual** |
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| **Protocol Disposition** |

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| **Accrual Summary** |
| **Arm Code** | **Consent Signed** | **On Study** | **On Treatment** | **Off Treatment** | **On Follow Up** | **Off Study** | **Expired** |
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| **Total** |  |  |  |  |  |  |  |

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| **Safety Summary** |

<List a summary of safety events or deviations that have occurred>

{Example text}

100 adverse events have occurred in 7 subjects.

50 adverse events were reported in the previous DISC report.

There have been no additional serious adverse events since the last DISC meeting.

Of the 50 adverse events, all were considered either mild or moderate.

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| **Deviations** |

<Insert a table of cumulative protocol deviations>

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| **Adverse Events** |

<Insert a table of cumulative adverse events>

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| **Serious Adverse Events** |

<Highlight any serious adverse events and the subsequent DISC acknowledgment date>